A prospective study of ultrasound scan–guided thrombin injection of femoral pseudoaneurysm: A trend toward minimal medication

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Background: **Catheterizations and endovascular procedures in which the femoral artery is cannulated are sometimes complicated by iatrogenic pseudoaneuryms. Surgical repair of pseudoaneurysms was the treatment of choice until 1991 when compression was used in those that were small. A less uncomfortable technique involving the ultrasound scan–guided injection of thrombin (UGTI) has been used more recently. The purpose of this study was to prospectively evaluate the effectiveness of ultrasound scan–guided thrombin injection (UGTI) as a treatment of iatrogenic femoral pseudoaneurysms.**

Methods: **From December 1998 to December 2000, 3734 femoral artery catheterizations were performed, and from those, 32 consecutive patients with 33 femoral pseudoaneurysms (0.88%) of less than 8 cm were prospectively enrolled for UGTI. With sterile technique, a 21-gauge or 22-gauge spinal needle was used to access the pseudoaneurysm and thrombin (100 to 6000 international units [IU]) was slowly injected until thrombosis occurred.**

Results: **The initial success rate was 100%. Thirty-one cases (93.9%) remained successfully thrombosed with a single injection at day 30. Recurrence of two pseudoaneurysms (6.1%) was seen at day 1 and day 8. One patient had groin cellulitis develop, and the other had a bleed into the thigh after discharge; both were treated with open surgical repair. Fifteen patients underwent UGTI on an outpatient basis with 100% successful ablation. More than half of the patients were on an inpatient basis (53.1%). Hospital stay was 1 to 9 days, with 88.2% of the patients released on day 1 or 2. However, two patients had a prolonged stay: one from open repair (day 9) and the other from a gastrointestinal bleed (day 8). Pseudoaneurysms ranged from 1.7 to 7.5 cm and lasted 1 to 17 days before UGTI. Twenty-one of the patients (65.7%) continued undergoing anticoagulant therapy at the time of injection. Ten of the last 11 cases needed less than 800 IU, and nearly half of the pseudoaneurysms (49%) successfully thrombosed with less than 600 IU. No procedural complications or mortality were noted. No statistical significance was found between occurrence of the pseudoaneurysm and sheath size (with χ^2 test, *P* value = .05) or between the size of the pseudoaneurysm and successful thrombosis (with χ^2 test: degrees of freedom, 6 − 1 = 5; *P* value = .227426). A mean follow-up period of 11.8 months was documented (range, 71 to 24 months). Seven patients were lost to follow-up at less than 30 days.**

Conclusion: **Percutaneous thrombin injection of iatrogenic pseudoaneurysms is an effective treatment. Not only is it minimally painful, but it can be done as an outpatient procedure and anticoagulation therapy does not hinder the success. Minimal thrombin seems necessary to successfully treat pseudoaneurysms that may further limit procedure-related complications. (J Vasc Surg 2002;36:779-82.)**

The incidence rate of femoral pseudoaneurysms has been documented between 0.05% and 4% but may increase up to 16% with more complex procedures that necessitate larger sheaths.[1-4] With the increased number of percutaneous interventions via femoral artery cannulation, the incidence rate of iatrogenic pseudoaneurysms has also increased. This has resulted in the development of alternative treatments for femoral pseudoaneurysms repair.

Open surgical repair was the gold standard for iatrogenic pseudoaneurysms until 1991. Fellmeth et al[5] reported on ultrasound scan–guided compression (UGCR), a nonsurgical intervention, for femoral pseudoaneurysms. UGCR proved to be a beneficial nonoperative technique for femoral pseudoaneurysms; however, it was painful for the patient and time consuming. UGCR had decreased success with larger pseudoaneurysms, those lasting greater than 2 weeks in duration, and those in patients who were undergoing anticoagulation therapy. Ultrasound scan–guided thrombin injection (UGTI) was first introduced in 1986 by Cope and Zeit[6] but only recently became increasingly popular. Hesitation possibly stemmed from potential intraarterial injection. Initial studies are encouraging, but continued prospective studies will aid in demonstrating the role of UGTI in the treatment of femoral pseudoaneurysms.

PATIENTS AND METHODS

Between January 1998 and December 2000, 3734 femoral catheterizations were performed in our institution. Thirty-three femoral pseudoaneurysms (0.88%) in 32 consecutive patients were treated with UGTI. Exclusion criteria included pregnancy, age less than 18 years, thrombin

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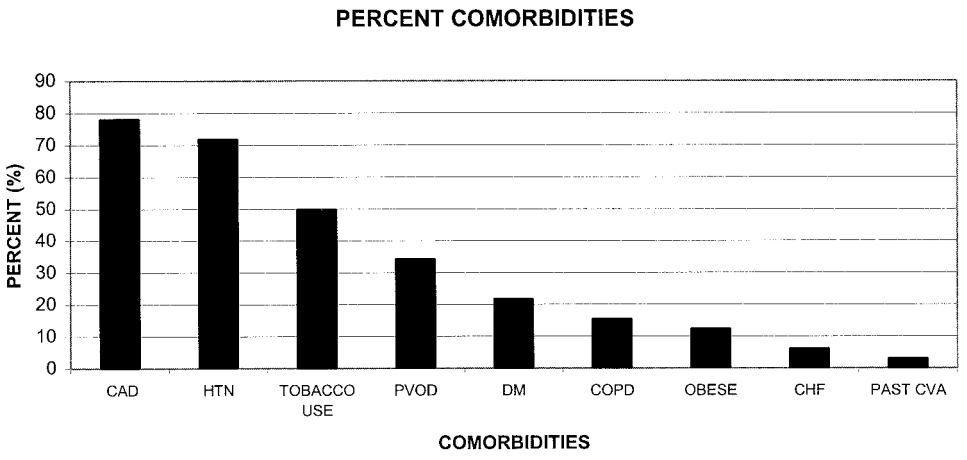

Patient comorbidities. *CAD,* Coronary artery disease; *HTN,* hypertention; *PVOD,* peripherovascular occlusive disease; *DM,* diabetes mellitus; *CHF,* congestive heart failure; *CVA,* cerebrovascular accident.

Sheath size correlation with occurrence of pseudoaneurysms on basis of totals of femoral artery catheterizations

Sheath size	*No. of catheterizations*	*No. of occurrences of PSAs*	*Percentage of PSA occurrence*
5F	272	0	0
6F	461	7	1.55
7F	1193	12	0.93
8F	1624	11	0.67
9F	107	2	1.86
10F	77	1	1.02
Totals	3734	33	0.88

4F and 11 to 14F not included.
χ^2: degrees of freedom, 6–1 = 5; *P* value, .227426. *P* value obtained is not less than .05 and therefore not statistically significant.
PSA, Pseudoaneurysm

allergy, or pseudoaneurysm more than 8 cm. Paraanastomotic pseudoaneurysms or those with active bleeding, shown clinically or with duplex scan, were surgically repaired. Also, those with compression of adjacent structures (ie, nerve, vein), evidenced by pain edema or skin necrosis, were excluded.

Diagnostic duplex scan was done with Agilent Sonos 55000 (Agilent Technologies, Andover, Mass) with 5-MHz to 7-MHz linear array transducer. Informed consent was obtained. Pedal pulses were assessed before and after the procedure. The groin was prepared and draped in the usual sterile fashion. Topical thrombin (Gen Trac, Middleton, Wis) had a concentration of 1000 U/mL in the initial five cases and then was decreased to 100 U/mL in the remaining cases. The concentration was loaded into a 10-mL syringe with either a 21-gauge or 22-gauge spinal needle attached. With direct ultrasound scan guidance, the tip of the needle was placed within the pseudoaneurysm and thrombin was slowly injected in 0.5-mL increments. Back pressure was maintained at the syringe plunger to prevent clotting of the needle. The injection of thrombin was performed with ultrasound scan guidance to confirm thrombosis of the sac and to ensure that the volume injected did not exceed the volume capacity of the pseudoaneurysm. Overfilling of the sac could result in potential spillage into the arterial system and promote subsequent thrombosis. Successful resolution was visualized within moments. Patency of the superficial femoral and profunda arteries was assessed with duplex scan, and distal pulses with Doppler scan evaluation. A pressure dressing was applied for 24 hours, and the patient was kept at bed rest for 2 to 6 hours. Repeat duplex scan was performed at 24 hours for inpatient procedures (n = 17) and at 1 week for outpatient procedures (n = 15). Patients were evaluated at 30 days and at each return visit to assess for persistent pulsatile groin mass and the presence of distal pulses.

RESULTS

Thirty-three femoral pseudoaneurysms in 32 patients were treated with UGTI. The patients (25 men; age range, 43 to 89 years; mean age, 69 years) had pseudoaneurysms develop from percutaneous cardiac (n = 22; 68.8%) or peripheral (n = 10; 31.2%) interventions; three of the peripheral cases were endoluminal grafts. The patient comorbidities are noted in the Fig. None of the cases were after failure of a percutaneous suture device. The pseudoaneurysm size ranged from a maximum diameter of 1.7 to 7.5 cm. Sheath size varied from 6F to 10F (Table). Duration of pseudoaneurysm before attempted ablation was 1 to 17 days (mean duration, 4.7 days). Forty-three percent of the cases were treated within 2 days, and 90% within 1 week.

Thirty patients (93.8%) were undergoing systemic anticoagulation therapy before the discovery of the pseudoaneurysm, and 21 (65.8%) continued to receive systemic anticoagulant therapy. None had the anticoagulant therapy reversed.

Initial success was seen with all 33 pseudoaneurysms (100%). Each case was injected on a single occasion. The volume of thrombin used ranged from 0.5 to 6.0 mL (mean volume, 2.3 mL). The 30-day success rate was 93.9%, with the recurrence of two pseudoaneurysms. No vascular complications, including thrombosis of distal vessels, occurred. No mortality occurred.

Recurrence of the pseudoaneurysm occurred in two of the 33 cases (6.1%), documented with duplex scan postprocedurally at day 1 and day 8, respectively. Both of these patients were obese and had chronic obstructive pulmonary disease (COPD). Both patients had had recent cardiac interventions and were taking antiplatelet agents. One patient had a failed second attempt at thrombin injection and had groin cellulitis develop, and hence, the vessel was repaired surgically. The other patient underwent repeat imaging before discharge, with successful thrombosis documented. Eight days later, this patient was readmitted with worsening lower extremity swelling. The groin was imaged to rule out deep venous thrombosis, and the pseudoaneurysm and a large hematoma were identified. This patient's hemoglobin level had decreased, and therefore, open surgical repair was selected. Twenty of the 21 patients (95.2%) who continued to receive systemic anticoagulation had successful ablation of their pseudoaneurysm. The one failure of the anticoagulated group (30 patients) was the pseudoaneurysm recurrence at day 1 in the patient with groin cellulitis.

Successful ablation was independent of pseudoaneurysm size or duration. No correlation was found between successful resolution of the pseudoaneurysm and the amount, or concentration, of thrombin injected. The minimal amount of thrombin necessary was 100 international units (IU). No statistical significance was found between the occurrence of the pseudoaneurysm and the sheath size used (with χ^2 test, P value = .227426). Fifteen of the 17 hospitalized patients (88.2%) were discharged on day 1 or 2 after the UGTI. The two remaining patients were discharged on day 8, after resolution of a gastrointestinal bleed, and on day 9, after open surgical repair for pseudoaneurysm recurrence at day 1. The patient readmitted for late recurrence (day 8) was hospitalized for 8 days for unrelated medical reasons. Fifteen patients underwent UGTI on an outpatient basis with 100% success. No patient had significant periprocedural pain or discomfort, which was managed when necessary with intravenous medications as deemed by the caregiver (vascular surgeon or physician assistant). A mean follow-up period of 11.8 months was completed (range, 1 to 24 months). Seven patients were lost to follow-up at less than 30 days.

DISCUSSION

Open surgical repair was the gold standard for iatrogenic pseudoaneurysms until 1991. Fellmeth et al[5] and Cox et al[7] reported on UGCR, a nonsurgical intervention, for femoral pseudoaneurysms. UGCR proved to be a beneficial nonoperative technique for femoral pseudoaneurysms; however, it was painful for the patient and time consuming and had limited success with anticoagulation therapy and larger pseudoaneurysms. UGTI was first introduced by Cope and Zeit[6] in 1986 but only recently has become increasingly popular. With UGTI, Liau et al[8] successfully treated five pseudoaneurysms in 1997, and the following year, Kang et al[9] showed a 95% success rate in 21 cases. In March 2000, Kang et al[10] published a series of 83 pseudoaneurysms (74 femoral) with an overall success of 96%. Most recently, Sackett et al[11] published a series of 30 UGTI with 1000 U/mL of thrombin and documented a 90% success rate and a 3% morbidity rate. Most of the past studies used 1000 IU/mL with each attempt at pseudoaneurysm thrombosis.

We showed increased success with UGTI compared with that of compression of larger pseudoaneurysms and those in patients undergoing anticoagulation therapy. No correlation was found between the size of the pseudoaneurysm and successful thrombosis (point biserial correlation, $t = 0.1416$). Anticoagulation therapy did not impair the success compared with UGCR.[7,12-14] Twenty of the 21 patients (95.2%) who continued to receive systemic anticoagulation had successful ablation of their pseudoaneurysm. The one failure of the anticoagulated group (30 patients) was the pseudoaneurysm recurrence at day 1 in the patient with groin cellulitis. We cannot comment whether there was increased success of longstanding pseudoaneurysms because the oldest one in our series was only present 17 days.

Early recurrence was minimal (6.1%). No late recurrence was documented with a mean follow-up period of 11.8 months. Of the two recurrences, a possible factor contributing to failure may have been increased intraabdominal pressure from severe COPD. Also, both patients were obese. The Fig documents patient comorbidities. Of the five patients with COPD, 40% (n = 2) had recurrent pseudoaneurysms develop, and of the four who were obese, 50% (n = 2) had recurrent pseudoaneurysms. No statistical significance was found between the occurrence of the pseudoaneurysm and size of sheath used (with χ^2 test, P value = 0.227426; Table).

A trend toward minimal medication is a striking observation in our series. The amount of volume injected into the femoral pseudoaneurysms can be increased while the low concentration is maintained. Past series have injected different amounts of thrombin concentrations with low volumes (ie, tuberculin syringes[9]), with a possible repeat of the injection if the initial attempt failed. In 10 of the last 11 cases, less than 800 IU of thrombin was necessary to successfully ablate the pseudoaneurysm. We found that volume besides concentration played an important role in larger pseudoaneurysms. As little as 100 IU was necessary in three pseudoaneurysms, and 200 IU in an additional seven pseudoaneurysms. Further research is necessary to determine whether the volume of thrombin injected rather than concentration is what correlates with successful thrombosis. The volume injected should never exceed the volume of the pseudoaneurysm because of potential spillage into the arterial system and subsequent thrombosis.

Lastly, UGTI is a cost-effective approach to iatrogenic femoral pseudoaneurysm ablation. A vial of 10,000 IU of thrombin is approximately $40.00. The costs of the ultrasound scan and actual procedure are estimated at $300.00 and $150.00, respectively. Thus, the total cost of UGTI is nearly $500.00. Open surgical repair of the artery is estimated at $980.00. Evacuation of a hematoma is as much as $690.00. These costs do not include the cost of anesthesia ($2000.00) or the hospitalization ($1000.00/day). These cost estimates overwhelming show UGTI to be a cost-effective treatment.

CONCLUSION

UGTI is a safe treatment of iatrogenic femoral pseudoaneurysms that has excellent results with little associated morbidity. UGTI is less painful and less time consuming than the previously used UGCR.

UGTI can be performed on an outpatient basis, which makes it a less costly approach to pseudoaneurysms than open surgical repair. Anticoagulation therapy is not a contraindication nor does it limit the success of UGTI. Lastly, successful thrombosis can be achieved with minimal amounts of thrombin, possibly limiting potential procedural morbidity.

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